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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,268	10/13/1999	ALEX CHENCHIK	CLON-008	7235

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	27

DATE MAILED: 06/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/417,268	Applicant(s) CHENCHIK, ALEX	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,53 and 57-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,53 and 57-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This action is in response to papers filed 11 April 2002 in Paper No. 26 in which claims 1, 6, 7, 13, 57, 58, 60, 65, 66 and 72 were amended. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 25 dated 8 January 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejection and new grounds for rejection.

Currently claims 1-17, 53 and 57-77 are under prosecution.

Specification

2. The amendment filed 11 April 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Applicant's attempt to incorporate by reference the Provisional Application to which priority is claimed is improper because the incorporation is not supported by the original disclosure. Applicant's claim to priority under 35 U.S.C. § 119(e) is supported by the Declaration filed with the original disclosure, but the original disclosure does not incorporate by reference the Provisional Application.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-17, 53, 57, 58 and 60-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Drmanac (U.S. Patent No. 6,308,824, filed 16 January 1997).

Regarding Claim 1, Drmanac discloses an array comprising at least on pattern of probe oligonucleotide spots attached to a surface of a solid support, wherein each probe spot consists of a mixture of a plurality of 2 or more unique oligonucleotides of different sequence that hybridize to the same target nucleic acid to produce a complex made up of said target nucleic acid and 2 or more unique oligonucleotides (Example 29, Column 54, lines 34-46).

Regarding Claim 2, Drmanac discloses the array wherein said plurality of unique oligonucleotides hybridize to different regions of said target nucleic acid i.e. non-overlapping (Column 54, lines 43-46).

Regarding Claim 3, Drmanac discloses the array wherein said plurality of unique oligonucleotides hybridize to non-overlapping regions of said target nucleic acid (Column 54, lines 43-46).

Regarding Claim 4, Drmanac discloses the array wherein said plurality of oligonucleotides hybridize to overlapping regions of the target (Column 54, lines 43-46).

Regarding Claim 5, Drmanac discloses the array wherein two or more different target nucleic acids are represented in said pattern (Example 29, Column 54, lines 33-46).

Regarding Claim 6, Drmanac discloses the array wherein each spot corresponds to a different target nucleic acid (i.e. each spot comprises a mixture of probes specific for target, Column 54, lines 34-46).

Regarding Claim 7, Drmanac discloses the array wherein two or more spots in said pattern correspond to the same target nucleic acid i.e. pathogenic organism genome (Example 29, Column 54, lines 8-11).

Regarding Claim 8, Drmanac discloses the array comprises a plurality of patterns i.e. arrays of probes (Column 1, lines 56-57).

Regarding Claim 9, Drmanac discloses the array wherein said plurality of patterns are separated from each other by walls (Example 15, Column 27, lines 22-40).

Regarding Claim 10, Drmanac discloses the array wherein each of said oligonucleotides ranges from about 15 to about 150 nucleotides in length (Column 27, lines 22-24).

Regarding Claim 11, Drmanac discloses the array wherein said array comprises at least one mismatch probe (Column 28, lines 54-65).

Regarding Claim 12, Drmanac discloses the array wherein said plurality ranges from about 3 to about 50 (Column 28, lines 12-22).

Regarding Claim 13, Drmanac discloses the array wherein said oligonucleotide spots correspond to the same type of target nucleic acid i.e. infectious agent (Example 29, lines 33-46).

Regarding Claim 14, Drmanac discloses the array wherein the spots do not exceed a density of about $1000/cm^2$ i.e. 1 to $25/mm^2$ (Column 19, lines 41-48).

Regarding Claim 15, Drmanac discloses the array wherein the spots do not exceed a density of about 400/cm^2 i.e. 1 to 25/mm^2 (Column 19, lines 41-48).

Regarding Claim 16, Drmanac discloses the array wherein the spots on the array range from about 50 to about 10,000 in number (Column 19, lines 41-63).

Regarding Claim 17, Drmanac discloses the array wherein the spots on the array range from about 50 to about 1,000 in number (Column 19, lines 41-63).

Regarding Claim 53, Drmanac discloses a kit comprising an array (Column 15, lines 31-39).

Regarding Claim 57, Drmanac discloses an array comprising a pattern of probe spots wherein each probe spot comprises a probe composition consisting of a mixture of 3 to 50 unique oligonucleotides of different sequences (Column 28, lines 12-22) and from about 15 to 150 nucleotides in length (Column 27, lines 22-24) that are each attached to a surface of a solid support and hybridize to a different region of the same target nucleic acid strand to producer a complex made up of said target and two or more unique oligonucleotides (Example 29, Column 54, lines 34-46).

Regarding Claim 58, Drmanac discloses an array comprising a pattern of probe spots of a density that does not exceed about 400 spots/cm^2, wherein each probe spot comprises a probe composition consisting of a mixture of 3 to 20 unique oligonucleotides of different sequences (Column 28, lines 12-22) and from about 25 to 100 nucleotides in length (Column 27, lines 22-24) that are each attached to a surface of a solid support and hybridize to a different region of the same target nucleic acid strand to producer a complex made up of said target and two or more unique oligonucleotides (Example 29, Column 54, lines 34-46).

Regarding Claim 60, Drmanac discloses an array comprising a pattern of probe spots wherein each probe spot comprises a probe composition consisting of a mixture of a plurality of 2 or more unique oligonucleotides of different sequences that are each attached to a surface of a solid support and cooperatively hybridize to a different region of the same target nucleic acid

strand to producer a complex made up of said target and two or more unique oligonucleotides (Example 29, Column 54, lines 34-46).

Regarding Claim 61, Drmanac discloses the array wherein said plurality of unique oligonucleotides hybridize to different regions of said target nucleic acid i.e. non-overlapping (Column 54, lines 43-46).

Regarding Claim 62, Drmanac discloses the array wherein said plurality of unique oligonucleotides hybridize to non-overlapping regions of said target nucleic acid (Column 54, lines 43-46).

Regarding Claim 63, Drmanac discloses the array wherein said plurality of oligonucleotides hybridize to overlapping regions of the target (Column 54, lines 43-46).

Regarding Claim 64, Drmanac discloses the array wherein two or more different target nucleic acids are represented in said pattern (Example 29, Column 54, lines 33-46).

Regarding Claim 65, Drmanac discloses the array wherein each spot corresponds to a different target nucleic acid (i.e. each spot comprises a mixture of probes specific for target, Column 54, lines 34-46).

Regarding Claim 66, Drmanac discloses the array wherein two or more spots in said pattern correspond to the same target nucleic acid i.e. pathogenic organism genome (Example 29, Column 54, lines 8-11).

Regarding Claim 67, Drmanac discloses the array comprises a plurality of patterns i.e. arrays of probes (Column 1, lines 56-57).

Regarding Claim 68, Drmanac discloses the array wherein said plurality of patterns are separated from each other by walls (Example 15, Column 27, lines 22-40).

Regarding Claim 69, Drmanac discloses the array wherein each of said oligonucleotides ranges from about 15 to about 150 nucleotides in length (Column 27, lines 22-24).

Regarding Claim 70, Drmanac discloses the array wherein said array comprises at least one mismatch probe (Column 28, lines 54-65).

Regarding Claim 71, Drmanac discloses the array wherein said plurality ranges from about 3 to about 50 (Column 28, lines 12-22).

Regarding Claim 72, Drmanac discloses the array wherein said oligonucleotide spots correspond to the same type of target nucleic acid i.e. infectious agent (Example 29, lines 33-46).

Regarding Claim 73, Drmanac discloses the array wherein the spots do not exceed a density of about $1000/cm^2$ i.e. 1 to $25/mm^2$ (Column 19, lines 41-48).

Regarding Claim 74, Drmanac discloses the array wherein the spots do not exceed a density of about $400/cm^2$ i.e. 1 to $25/mm^2$ (Column 19, lines 41-48).

Regarding Claim 75, Drmanac discloses the array wherein the spots on the array range from about 50 to about 10,000 in number (Column 19, lines 41-63).

Regarding Claim 76, Drmanac discloses the array wherein the spots on the array range from about 50 to about 1,000 in number (Column 19, lines 41-63).

Regarding Claim 77, Drmanac discloses a kit comprising an array (Column 15, lines 31-39).

5. Claims 1-4, 7, 8, 11, 13, 16, 60-63, 66, 67, 70, 72 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Gentalen et al (U.S. Patent No. 6,306,643, filed 24 August 1998).

Regarding Claim 1, Gentalen et al disclose an array comprising at least on pattern of probe oligonucleotide spots attached to a surface of a solid support, wherein each probe spot consists of a mixture of a plurality of 2 or more unique oligonucleotides of different sequence

that hybridize to the same target nucleic acid to produce a complex made up of said target nucleic acid and 2 or more unique oligonucleotides (Column 8, lines 46-65).

Regarding Claim 2, Gentalen et al disclose the array wherein said plurality of unique oligonucleotides hybridize to different regions of said target nucleic acid i.e. non-overlapping (Column 14, lines 17-21).

Regarding Claim 3, Gentalen et al disclose the array wherein said plurality of unique oligonucleotides hybridize to non-overlapping regions of said target nucleic acid (Column 14, lines 17-21).

Regarding Claim 4, Gentalen et al disclose the array wherein said plurality of oligonucleotides hybridize to overlapping regions of the target (Column 12, lines 45-64).

Regarding Claim 7, Gentalen et al disclose the array wherein two or more spots in said pattern correspond to the same target nucleic acid i.e. same polymorphic site (Column 12, lines 45-64).

Regarding Claim 8, Gentalen et al disclose the array comprises a plurality of patterns i.e. plurality of cells (Column 11, lines 12-25).

Regarding Claim 11, Gentalen et al disclose the array wherein said array comprises at least one mismatch probe (Column 14, lines 27-32).

Regarding Claim 13, Gentalen et al disclose the array wherein said oligonucleotide spots correspond to the same type of target nucleic acid i.e. same polymorphic site (Column 12, lines 45-64).

Regarding Claim 16, Gentalen et al disclose the array wherein the spots on the array range from about 50 to about 10,000 in number (Column 11, lines 15-17).

Regarding Claim 60, Gentalen et al disclose an array comprising a pattern of probe spots wherein each probe spot comprises a probe composition consisting of a mixture of a plurality of 2 or more unique oligonucleotides of different sequences that are each attached to a surface of a solid support and cooperatively hybridize to a different region of the same target

nucleic acid strand to produce a complex made up of said target and two or more unique oligonucleotides (Column 8, lines 46-64).

Regarding Claim 61, Gentalen et al disclose the array wherein said plurality of unique oligonucleotides hybridize to different regions of said target nucleic acid i.e. non-overlapping (Column 14, lines 17-21).

Regarding Claim 62, Gentalen et al disclose the array wherein said plurality of unique oligonucleotides hybridize to non-overlapping regions of said target nucleic acid (Column 14, lines 17-21).

Regarding Claim 63, Gentalen et al disclose the array wherein said plurality of oligonucleotides hybridize to overlapping regions of the target (Column 12, lines 45-64).

Regarding Claim 66, Gentalen et al disclose the array wherein two or more spots in said pattern correspond to the same target nucleic acid i.e. same polymorphic site (Column 12, lines 45-64).

Regarding Claim 67, Gentalen et al disclose the array comprises a plurality of patterns i.e. plurality of cells (Column 11, lines 12-25).

Regarding Claim 70, Gentalen et al disclose the array wherein said array comprises at least one mismatch probe (Column 14, lines 27-32).

Regarding Claim 72, Gentalen et al disclose the array wherein said oligonucleotide spots correspond to the same type of target nucleic acid i.e. same polymorphic site (Column 12, lines 45-64).

Regarding Claim 75, Gentalen et al disclose the array wherein the spots on the array range from about 50 to about 10,000 in number (Column 11, lines 15-17).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac (U.S. Patent No. 6,309,824, filed 16 January 1997) in view of Stratagene (catalog, 1989, page 39).

Regarding Claim 59, Drmanac teaches a kit comprising an array (Column 15, lines 31-39) and they teach a hybridization method comprising the array and reagents for generating a labeled target nucleic acid sample (Example 5, Columns 13-14) but they do not specifically teach their kit comprising the reagents for generating a labeled nucleic acid sample. However, Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method components of Drmanac into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

8. No claim is allowed.

9. The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 19, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600